

IRB APPLICATION INSTRUCTIONS

Reading these instructions will help you to prepare your application to the IRB. It is in your best interest to read them carefully, so that the review of your application will proceed smoothly and efficiently. Thank you!

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Section I

Requirements for Submission

All research involving human subjects at IIT is subject to review by the IIT Institutional Review Board (IRB) for the Protection of Human Subjects.

All IRB protocol applications and supporting material must be typed. Handwritten applications will be returned without being considered.

Requirements for the submission of protocol applications vary with the type of research involved. While some protocol applications will require review by the convened IRB committee, federal law states that research using human subjects in certain restricted ways may be eligible for expedited review. (Consult **Section II** of these instructions to determine whether your research falls into any of the six categories of research that are eligible for expedited review.)

- If your research qualifies for **expedited review**, one original (single-sided) protocol application and two (double-sided) copies may be submitted at any time to the Office of Research Compliance (Main Building—Room 301). To allow adequate time for review, the protocol application and supporting documents should be submitted to the IRB office no later than 30 days prior to the project's anticipated start date.
- If your application requires **full IRB review**, you must submit one original (single-sided) protocol application and eleven (double-sided) copies to the Office of Research Compliance (Main Building—Room 301) prior to the monthly deadline shown on the IRB webpage: (http://www.iit.edu/research/services/orcpd/ORCPD_SubmissionDeadlines.shtml). The deadline for submission is 5:00pm on the date indicated and will be strictly enforced. If you miss the deadline, your IRB submission will be reviewed at the following scheduled meeting.

Important Note: The materials and documentation brought before the convened IRB should be finished products, not works in progress. The convened committee is not the place to review a rough draft or to finalize your research plan. All necessary information must be entered in the IRB application format. Do not simply copy text from a grant application or refer to grant sections that are attached as appendices. An Investigator with authority to revise the protocol must be present at the meeting at which the protocol is reviewed. The Investigator attending the meeting will be asked to provide a brief summary of the research, even if the application is a renewal and the research has been previously approved.

IRB approval is valid for one year. If a project continues beyond the approval expiration data, the investigator(s) must submit an application and appropriate copies every year for review and approval.

If you have any questions, please call Glenn Krell MPA, CRA (312) 567-7141 or Dr. Scott Morris (312) 567-5932, Institute of Psychology, who is Chairperson of the IRB. IRB policies, procedures and other related documents can be found on the web at <http://www.grad.iit.edu/research/irbhome.html>.

Section II

Is my Research Eligible for Expedited Review?

IS THIS HUMAN SUBJECTS RESEARCH?

Ascertain whether or not your project is defined as human research by reviewing the two definitions below and determining whether each applies. If both definitions apply to your research, you are involved in research with human subjects. If only one or neither definition applies to your research, you are not involved in human subjects in research and likely do not require IRB review.

- **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge.
- **Human Subject** means a living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.

IS THIS HUMAN SUBJECTS RESEARCH ELIGIBLE FOR EXPEDITED REVIEW?

Under certain circumstances, research involving human subjects is exempt from Federal regulation requiring full IRB review. If your research activities involve human subjects and fall entirely within the parameters of one or more of the following categories, please check the corresponding box(es) in **Section A, Question 13** of the Application.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) Research on regular and special education instructional strategies; (ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under {condition 2} if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publically available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) Procedures for obtaining benefits or services under those programs; (iii) Possible changes in or alternatives to those programs or procedures; or (iv) Possible changes in methods or levels of payment for benefits or services under these programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) If wholesome foods without additives are consumed or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

Section III **Students as Subjects**

IRB Policy on Student Participation as Subjects in Research

This policy applies to recruitment of students when participation as a subject in research is a requirement for a course or is a basis for extra credit in a course. Such recruitment is acceptable when:

1. Participation in research is one of several persuasively comparable options available to a student for fulfilling the course requirement or obtaining optional course credit;
2. Students are informed of the availability of alternatives prior to or at the time of recruitment, and as part of the informed consent process.
3. When research participation is a course requirement, the research experience must be judged by the academic unit to be relevant to the course and have educational value. This determination is not required for courses offering only extra credit.

While the course instructor has discretion in determining course credit and appropriate alternatives to research participation, it is the responsibility of the researcher to take reasonable steps to ensure that alternatives are offered and credit is awarded in compliance with this policy.

Section IV **Confidentiality and Disposal of Identifying Information**

IRB Policy on Maintenance and Disposal of Identifying Records:

Identifying records that are linked to research data (e.g. names, social security numbers, video recordings, etc.) should be maintained in a secure location, and only as long as required for completion of the research. It is expected that all identifying records will be disposed of within no more than six years after the data are collected in a manner that protects participant confidentiality.

IRB Policy on Maintenance and Disposal of Informed Consent Documents:

Signed consent documents represent a record that can link participants to the research, and therefore should be treated with the same care given to other identifying information. Signed consent documents should be maintained by the researcher(s) in a secure location for six years after the subject has completed research participation. After six years, the documents should be disposed of in a manner that protects participant confidentiality.

Section V

Informed Consent

Informed consent is a legal requirement for research involving human subjects:

'No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.' (45 CFR 46.116).

If the subject is a minor, at least verbal assent should be obtained from the child in addition to the required written consent by the parent/guardian. The language of the consent form should be non-technical and understandable to all subjects who will be requested to consent to participate. A list of simple language appropriate for consent documents can be found at the following link:
<http://www.seattlechildrens.org/doc/glossary-resource.doc> .

Each subject must be given a consent document, whether or not the procedure includes collecting a signature on the form. The requirement of signed consent may be waived in instances where (1) the only record linking the subject to the research would be the consent document and (2) the principal risk would be potential harm resulting from a breach of confidentiality.

The following elements must appear in your consent form:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject. 'Risk' and 'discomfort' include psychological as well as physiological effects.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimal risk, an explanation as to whether any compensation will be given and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject. This should include the name and phone number of the Principal Investigator(s) and the Executive Officer of the IIT Institutional Review Board (Glenn Krell, 312-567-7141).
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits or services to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty.
9. A statement that absolves IIT of responsibility for any injuries or medical conditions that may be suffered by the participant during the course of the research unless those injuries or medical conditions are due to IIT's negligence.
10. A statement that the participant has received a copy of the consent form.

11. Any consent form distributed to a research subject must be approved and stamped by the IIT IRB executive office.

Note: It is preferable to use the title of 'Consent Document' rather than 'Informed Consent' on your consent form.

SAMPLE CONSENT FORM

(This is only a sample. Do not copy portions unless they apply to your research.)

CONSENT DOCUMENT

I understand that my participation in this research study is voluntary and that I may withdraw from the study at any time without penalty. I also understand that my identity will be coded to ensure confidentiality.

As a participant in this study, I will spend approximately ½ hour today for interviewing and completing questionnaires, and approximately one hour in a psychophysiological research laboratory during a subsequent session.

While in the laboratory, sensors will be placed on my finger to measure blood flow, a blood pressure cuff will be placed on one bicep muscle to measure blood pressure, and electrodes will be placed on my right wrist and left ankle to measure heart rate. I have been informed that these measurement procedures are standard and should involve no discomfort. During the study, I will be asked to complete an information processing task for several minutes.

As part of today's session, I will be measured for height, wrist circumference, weight, and blood pressure and complete several questionnaires concerning coping style and life stress. I will also be interviewed concerning my exercise habits, diet, smoking, and general medical health. Additionally, I give my permission to have my parents contacted in regard to their blood pressure history.

Although participation involves no future obligation, I will be contacted for future assessment sessions involving identical procedures and will have the opportunity to participate in additional research if I so wish. I also understand that I will be paid \$10 for my participation in the session.

I understand that this research presents no risks other than what I might feel from thinking about the questions that are asked. I understand that the IIT Counseling Center is available to me, free of charge, to discuss my situation or my feelings. IIT Counseling Center can be contacted at 312-567-5900.

Experimental procedures have been explained to me and I have a satisfactory understanding of them. Any further questions about the research and my rights as a participant will be answered if I contact the project director {Name, Department, Number/Email}.

I understand that the Illinois Institute of Technology is not responsible for any injuries or medical conditions I may suffer during the time I am a research participant unless those injuries or medical conditions are due to IIT's negligence. I may address questions and complaints to Glenn Krell, MPA, CRA, Executive Officer of IIT Institutional Review Board at 312-567-7141.

I have read the material above and any questions I asked have been answered to my satisfaction. I agree to participate in this activity, realizing that I may withdraw without penalty at any time.

I have received a copy of the consent form.

Subject Signature

Date

This consent form is valid only if stamped by Executive Officer of IIT IRB.

*Please note the above consent form is sample language only. IIT Counseling Services are only available to IIT students. If you subjects are not IIT students, you must refer them to appropriate resources.

Section VI

Risk

The concept of risk goes beyond physical risk, and includes risk to the subject's dignity and self-respect, as well as psychological, emotional, or behavioral risk. *Minimal risk* means that the risks of harm anticipated are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Section VII

Ethics in Research

Mandatory Training Requirement: All IIT Personnel working with human subjects must complete a training module on human subjects research. This policy is part of IIT's ongoing commitment to the responsible and ethical conduct of research. The training process takes approximately 2 hours. At the end of the completed training process, participants are issued a certificate. This certificate must be printed out and kept in your files. A copy of the certificate should be attached to the IRB application. Training is required on an annual basis.

Training link: <http://phrp.nihtraining.com/users/login.php>.

If you have previously completed the training module and are having difficulty obtaining a new certificate:

1. Log in to the course at: <http://phrp.nihtraining.com/index.php>
2. Click the link labeled 'Edit User Info' on the Main Menu page
3. Click the button labeled 'Retake Course'

Ethical Guidelines from DHS OHRP (Office of Human Research Protections): You may obtain OHRP Reports via the following website:

http://www.iit.edu/research/services/orcpd/Education_Material_Research.shtml

Ethics in Research: A Resource Guide for Graduate Students: At IIT we strive to foster and encourage an ethical climate for all who conduct research, including our graduate students. This Web page of resources on ethical issues in research was created in order to provide you with guidance to help you make good judgments about how to conduct your research. The page may be accessed via this link:

http://www.iit.edu/research/services/orcpd/ethics_in_research.shtml

For more information, please call the Office of Research Compliance and Proposal Development at 312-567-7141.